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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,852	03/21/2002	Andrew Austen Mortlock	Z70600-1	2243

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,852	MORTLOCK ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-21-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claim 1 recites the limitation of "*ester, amide or prodrug thereof*" which renders the claims indefinite because of the broad limitation of "*prodrug*" together with narrows limitations of "ester, amide".

b. Claims 5-7 are indefinite because they recite the definition of R^{42} which includes a broad limitation of "*an aromatic heterocyclic group*...." together with the narrow limitation of "*pyridone*".

c. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad

language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

d. Claim 12 recites the step of "*converting any precursor groups* $R^{1'}$, $R^{2'}$, $R^{3'}$, $R^{4'}$ *or* $R^{5'}$ *to groups* R^1, R^2, R^3, R^4 *or* R^5 *respectively, or changing a group* R^5 *to a different such group*." Said limitation renders the claim indefinite because "$R^{1'}$, $R^{2'}$, $R^{3'}$, $R^{4'}$ *are groups* R^1, R^2, R^3, R^4". Thus, it is unclear what features of $R^{1'}$, $R^{2'}$, $R^{3'}$, $R^{4'}$ get converted. Likewise, the limitation of "*changing a group* R^5 *to a different such group*" does not have definite metes and bounds because it is unclear which R^5 group is converted to which.

e. **Use Claim:** Claim 13 provides for the use of "a compound of the formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast cancer, does not reasonably provide enablement for the treatment of all other diseases embraced by claim 14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

a. **The breadth of the claim**: Claim 14 recites "a method for inhibiting aurora 2 kinase…" which is drawn to the treatment of known and unknown diseases for which no enablement is provided. Even if the intended disorders are "proliferative diseases" or

cancers, the scope of the claim still encompasses a plethora of diseases that do not share the same etiology, locality (i.e., tissue, or organ), and/or manifestation. Furthermore, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no prior art for assuming such a common activity. See ***In re Surrey***, 151 USPQ 724 regarding sufficiency of the disclosure for a Markush group.

b. **The amount of direction or guidance presented**: The specification provides assays and procedures to determine the inhibitory activity on aurora 2 kinase. However, the specification does not provide correlation between the *in vitro* data to the treatment of various cancers or proliferative disorders which fall within the scope of the claim. Moreover, the specification does not provide guidance on how a patient in need of aurora 2 kinase can be identified, or which proliferative disorder or cancer is related to aurora 2 kinase. The enzyme activity is generally unpredictable, and highly structure specific. Thus, if only a limited number of compounds could inhibit aurora 2 kinase, it does not mean the entire genus of formula I would be able to inhibit the same enzyme. See MPEP 2164.03 regarding enablement requirements in cases directed to structure specific arts such as the pharmaceutical art. Likewise, if the inhibition of aurora 2 kinase can treat one type of cancer or proliferative disorder, it does not mean the same activity can treat the whole array of proliferative disorders or cancers.

c. **The state of the prior art**: Currently, there is no one compound that can treat cancers of all types generally. Different types of cancers affect different organs, and have different methods of growth and harm to the body. Thus, the existence of a "silver bullet" to treat a myriad of proliferative disorders or cancers is contrary to the practice of oncology. See ***In re Butting***, 163 USPQ 689 (CCPA 1969), wherein 'evidence involving a single compound and two types of cancers'.

d. **The predictability or unpredictability of the art**: The process of mitosis, particulary the activity of microtubules, is poorly understood. Also, the selective release of chromosome cohesion during cell division is unclear. Therefore, the treatment of proliferative disorders or cancers in general is highly unpredictable. Since there is no correlation between the activity of microtubules or chromosome cohesion and the inhibition of aurora 2 kinase, a method of treatment based on such an activity is very speculative.

Given the unpredictable nature of the art, and the limited guidance, the skilled clinician would have to (first) establish a relationship between aurora 2 kinase with a particular cancer or proliferative disorder, then figure out which of the claimed compounds is actually effective. Such as task would require undue experimentation.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. **Use Claim:** Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

4. Claims 1, 5-7 are also objected to because of the following informalities: unmatched parentheses are found in said claims (e.g., claim 1, page 66, line 5; claim 5 items 2 & 4; claim 6, items 3, 5, 9, 14, 15, and 22; claim 7, item 16'). Appropriate correction is required.

5. Claims 4 and 9 are also objected to under 37 CFR 1.75(c) as being in improper form because they refer to two sets of claims for different features. See MPEP § 608.01(n).

Specification

6. The disclosure is objected to because of the following informalities: unmatched parentheses are found in several places.

Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-T (~10 am ~ 8:30 pm) starting from February 22nd, 2004.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong
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March 18, 2004